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10/560,519	03/20/2006	Inge Dorthe Hansen	HOI-14302/16	5664

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,519	HANSEN, INGE DORTHE	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 30-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 30-55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 05/24/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 30-55 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 31 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the phrase "administering an effective amount of a medicament". However, the claim is indefinite because, it is unclear whom, what or who the recipient of the medicament is intended to be. Consequently, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Regarding claim 31, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 35 recites the phrase "preferably selected from lactose". However, the claim is indefinite because, it is unclear how a saccharide can be preferably selected from lactose (which is a single saccharide).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

(1) field of the invention

(2) breath of the claims, and

(3) possession of the claimed invention at the time of filing for each claimed species/genus based upon the teachings of the specificaiton and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally known to exist, in the absence as to what the material consists of is not a definition of that material". Id. Further, the court stated that to adequately describe a claimed genus, adequate

must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". Id .

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

Claim 30 is drawn to a method for the treatment, amelioration and/or prophylaxis of one or more symptoms associated with bacterial vaginosis, comprising administering an effective amount of a medicament comprising a saccharide, said saccharide being fermented by lactic acid bacteria, wherein the medicament comprises at least 20 percent by weight of said saccharide, and wherein the medicament is substantially free from bacteria. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive (prophylactic) therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed. Applicant claims a method for the prevention (prophylaxis) of the symptoms associated with bacterial vaginosis, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said disease, which is seen to be lacking a clear description via art recognized procedural and methodological steps. In addition, the said disease is not known to have a single recognized cause. Moreover, the exact cause of bacterial vaginosis is unknown (see Schwebke et al., page 62, 1st col., last paragraph). Furthermore, most women with bacterial vaginosis do not have any symptoms. In fact, the aforementioned disease, is recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices

such as the diet and maintenance of bodily healthiness which includes (1) personal hygiene (2) change in the normal bacteria of the vagina (3) douching (4) using an intrauterine device (IUD) for birth control (5) using too many perfumed soaps or bubble baths. These are only a few of the factors that promote these diseases in people. It is important to note that bacterial vaginosis reoccurs in some women and since it is unclear why or how these recurrences or relapses occur, it not possible to predict the time of such reoccurrence so as to attempt to provide any preventative methods of treatment. Applicant has not provided a description as to how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be prevented. Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by said diseases. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed methods with a reasonable expectation of success. Therefore, the prevention or prophylaxis of the said disease much less said symptoms in a patient is not enabled by the instant disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53-55 are rejected under 35 U.S.C. 102(b) as anticipated by Woitun et al. (DE 1959402 A) (Abstract Only).

In claim 53, applicant claims a pharmaceutical composition for vaginal application, comprising a saccharide, wherein the saccharide constitutes at least 20 percent by weight of the pharmaceutical composition, and wherein the composition is substantially free from bacteria. Woitun et al. disclose applicant's composition for vaginal use comprising a saccharide (lactose), wherein the saccharide constitutes at least 20 percent by weight of the composition, and wherein the composition is substantially free from bacteria (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for vaginal application, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claim 54 which is drawn to a kit comprising the pharmaceutical composition of claim 53 and an anti-fungal and/or an anti-bacterial agent for simultaneous, sequential or separate use, is anticipated by Woitun et al. since Woitun et al.'s composition also contains an antifungal/antibacterial agent (see abstract). It should be noted that the kit does not add to the patentability of the composition claimed. It should be noted that it is well settled that "intended use" of a composition or product, e.g., for vaginal application, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claim 55 which is drawn to a kit-of-parts comprising the pharmaceutical composition as defined in claim 53 and at least one pH measurement means, for measuring vaginal pH, is anticipated by Woitun et al. (see abstract). It should be noted that the kit does not add to the patentability of the composition claimed. It

should be noted that it is well settled that "intended use" of a composition or product, e.g., for vaginal application, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ozmen et al.(Turkish Journal of Medical Sciences (1998), 28 (2), pages 171-173) (Abstract Only).

In claim 30, applicant claims a method for the treatment, amelioration and/or prophylaxis of one or more symptoms associated with bacterial vaginosis, comprising administering an effective amount of a medicament comprising a saccharide, said saccharide being fermented by lactic acid bacteria, wherein the medicament comprises at least 20 percent by weight of said saccharide, and wherein the medicament is substantially free from bacteria. Ozmen et al. disclose applicants' method for the treatment of symptoms associated with bacterial vaginosis,

comprising administering an effective amount of a medicament comprising a saccharide (lactose suppository) (see abstract). It should be noted that Ozmen et al. is silent about the percent by weight of said saccharide in the composition or medicament. However, the silence of Ozmen et al. do not mean that Ozmen et al.'s composition does not contain the same percent by weight of said saccharide, especially since Ozmen et al. disclosed that their composition is a lactose suppository. Ozmen et al. anticipates the claims if their composition contains the same percent by weight of said saccharide and Ozmen et al. renders the claims as being obvious if the percent by weight of said saccharide in their composition is substantially close to the percent by weight of said saccharide in applicant's claimed composition. It should be noted that fermented lactose does not render applicant's lactose as been different from Ozmen et al.'s lactose since said fermented saccharide is still a saccharide as claimed by applicant with no chemical or structural difference. Claims 31-39 which are drawn said method involving specific symptoms, saccharides (including lactose) and composition comprising specific percentage by weight of saccharide are also encompassed by this rejection as set forth above since, the silence of Ozmen et al. about specific symptoms and composition comprising specific percentage by weight of saccharide do not mean that Ozmen et al.'s composition does not contain the same percent by weight of said saccharide, nor treat the same symptoms, especially since Ozmen et al. disclosed that their composition is a lactose suppository which treats symptoms. Claims 40-41 which are drawn to said method wherein the bacterial vaginosis has specific cause are also encompassed by this rejection since said cause of bacterial vaginosis is the same (Garderella vaginalis) as Ozmen et al.'s and said symptom and not said cause is being treated. Claims 42 and 43 which are drawn to said method involving specific forms of said composition are also encompassed by the above

rejection since Ozmen et al. uses the same form of the composition as the applicant (see abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 44-48, 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ozmen et al.(Turkish journal of Medical Sciences (1998), 28 (2), pages 171-173) (Abstract Only).

Claims 44-46 are drawn to the method of claim 30, wherein the medicament is in the form of a vaginal capsule, tablet or suspension. Claims 47-48 are drawn to the method of claim 30, wherein the medicament is of specific dosage unit.

Ozmen et al. disclose applicants' method for the treatment of symptoms associated with bacterial vaginosis, comprising administering an effective amount of a medicament comprising a saccharide (lactose suppository) (see abstract). It should be noted that Ozmen et al. is silent about the percent by weight of said saccharide in the composition or medicament. However, the silence of Ozmen et al. do not mean that Ozmen et al.'s composition does not contain the same percent by weight of said saccharide, especially since Ozmen et al. disclosed that their composition is a lactose suppository. Ozmen et al. anticipates the claims if their composition contains the same percent by weight of said saccharide and Ozmen et al. renders the claims as being obvious if the percent by weight of said saccharide in their composition is substantially

close to the percent by weight of said saccharide in applicant's claimed composition. It should be noted that fermented lactose does not render applicant's lactose as been different from Ozmen et al.'s lactose since said fermented saccharide is still a saccharide as claimed by applicant with no chemical or structural difference.

The difference between applicant's claimed method and the method of Ozmen et al. is the form of the composition used. However, it is obvious to prepare Ozmen et al.'s composition in different forms such as capsule, tablet or suspension that are commonly used in the art based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared and administer Ozmen et al.'s composition in different forms such as capsule, tablet or suspension that are commonly used in the art, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

One having ordinary skill in the art would have been motivated to prepare and administer Ozmen et al.'s composition in different forms such as capsule, tablet or suspension that are commonly used in the art, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. It should also be noted that the preparation oral formulations of composition in forms such as tablets, capsules, suspensions, or liquid formulations are well within the purview of a skilled artisan. Also, it should also be noted that the use of specific dosage units

depend on factors such as the type and severity of the symptom or condition and type, mass and age of individual treated.

Claims 51-52 are drawn to said method wherein the medicament or composition further includes an effective amount of antibacterial agent and specific antibacterial agent including metronidazole.

Ozmen et al. disclose applicants' method for the treatment of symptoms associated with bacterial vaginosis, comprising administering an effective amount of a medicament comprising a saccharide (lactose suppository) (see abstract). It should be noted that Ozmen et al. is silent about the percent by weight of said saccharide in the composition or medicament. However, the silence of Ozmen et al. do not mean that Ozmen et al.'s composition does not contain the same percent by weight of said saccharide, especially since Ozmen et al. disclosed that their composition is a lactose suppository. Ozmen et al. anticipates the claims if their composition contains the same percent by weight of said saccharide and Ozmen et al. renders the claims as being obvious if the percent by weight of said saccharide in their composition is substantially close to the percent by weight of said saccharide in applicant's claimed composition. It should be noted that fermented lactose does not render applicant's lactose as been different from Ozmen et al.'s lactose since said fermented saccharide is still a saccharide as claimed by applicant with no chemical or structural difference. Furthermore, Ozmen et al. disclose that the antibacterial agent, metronidazole can be used to treat said symptoms of bacterial vaginosis (see abstract).

The difference between applicant's claimed method and the method of Ozmen et al. is the applicant composition further comprises an effective amount of antibacterial agent including

metronidazole. However, Ozmen et al. disclose that the antibacterial agent, metronidazole can be used to treat said symptoms of bacterial vaginosis (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared and administer a composition comprising a combination of saccharide (lactose) and the antibacterial, metronidazole taught by Ozmen et al. in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated to prepare and administer a composition comprising a combination of saccharide (lactose) and the antibacterial, metronidazole taught by Ozmen et al. in order to treat the symptoms associated with bacterial vaginosis, based of factors such as the type and severity of the symptom or condition and type and age of individual treated, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

Claims 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ozmen et al. (Turkish journal of Medical Sciences (1998), 28 (2), pages 171-173) (Abstract Only) in combination with Lin et al. (US 2003/0017207 A1).

Claims 49-50 are drawn to said method wherein the medicament or composition further includes an effective amount of antibacterial agent and specific antibacterial agent.

Ozmen et al. disclose applicants' method for the treatment of symptoms associated with bacterial vaginosis, comprising administering an effective amount of a medicament comprising a saccharide (lactose suppository) (see abstract). It should be noted that Ozmen et al. is silent about the percent by weight of said saccharide in the composition or medicament. However, the silence of Ozmen et al. do not mean that Ozmen et al.'s composition does not contain the same percent by weight of said saccharide, especially since Ozmen et al. disclosed that their composition is a lactose suppository. Ozmen et al. anticipates the claims if their composition contains the same percent by weight of said saccharide and Ozmen et al. renders the claims as being obvious if the percent by weight of said saccharide in their composition is substantially close to the percent by weight of said saccharide in applicant's claimed composition. It should be noted that fermented lactose does not render applicant's lactose as been different from Ozmen et al.'s lactose since said fermented saccharide is still a saccharide as claimed by applicant with no chemical or structural difference. Furthermore, Ozmen et al. disclose that the antibacterial agent, metronidazole can be used to treat said symptoms of bacterial vaginosis (see abstract).

The difference between applicant's claimed method and the method of Ozmen et al. is the applicant composition further comprises an effective amount of antifungal agent.

Lin et al. disclose that the antifungal agents can be used to treat vaginosis (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared and administer a composition comprising a combination of Ozmen et al.'s saccharide (lactose) and an antifungal as taught by Lin et al. in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. More specifically, it is obvious

to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated to prepare and administer a composition comprising a combination of Ozmen et al.'s saccharide (lactose) and an antifungal as taught by Lin et al. in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

January 3, 2007.

SAQ 1/4/08

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